REMARKS

In the 22 April 2004 Office Action, the Examiner allowed claims 88, 90, 91, 93-95, and 99; objected to claim 97, but indicated it would be allowable if rewritten in independent form; and rejected claims 32-36, 65, 66, 68, 70-76, 78-87, 92, 96, and 98 as anticipated by US Patent 5,031,634 ("Simon") or obvious over Simon in view of US Patent 4,643,196 ("Tanaka") or US Patent 4,799,495 ("Hawkins"). The undersigned respectfully submits that all pending claims are allowable over the applied references and requests reconsideration.

I. Amendment

The present amendment amends claims 32, 35, 36, 65, 66, 71-73, 75, 80, 83, 92, 96, and 98. The amendments to claim 96 generally corresponds to prior claim 97, which the Examiner indicated was allowable. Accordingly, claim 96 is allowable over the applied references.

II. Applied Art

Simon suggests a biopsy needle-guide that employs a staple-like pincer arrangement, shown in Figures 6 and 7, to hold the biopsy guide in place. This "staple-like action" (column 4, lines 22-23) is central to Simon's goal of overcoming the stated problems associated with the prior art approaches described in columns 1-3. Two classes of these described devices employ "hookwires," with one class being retractable and the other not designed for retraction. Simon contends that each of these hookwire devices suffers from several problems. For example, Simon characterizes the Homer localizer as problematic because a curved wire damages tissue with "a scythe-like action." Simon faults other hookwire designs for risking unintended penetration of the tissue or from risking being severed.

To overcome these difficulties, Simon employs a pincer design that grips tissue between two opposed barbs. The opposing action of the barbs limits accidental advancement further into the tissue. The barbs are carried on thick, half-round wires that

substantially fill the lumen of the cannula to reduce the risk of severing the wires. (Column 4, lines 58-61.) The cannula 12 that carries the wires is hollow and has an open end 18, as best seen in Figures 6 and 7. In the position illustrated in Figures 1-3, a sharpened tip 52 of wire 50 protrudes through this open end to aid in positioning, but the sharpened tip is retracted within the cannula 12 when the pincer is deployed (Figures 6 and 7).

III. Claims 32-36, 65, 66, 68, and 70-74

The tissue anchor of claim 32 includes an elongate tube that has a central bore, a closed distal end, a proximal end, and at least first and second apertures angularly spaced about a circumference of the tube. An elongate member has a portion sized for receipt and axial movement in the central bore between a first position and a second position. First and second anchor members are attached to the portion of the elongate member. The first anchor member includes a first free distal end carrying a first tissue-penetrating barb and the second anchor member includes a second free distal end carrying a second tissue-penetrating barb. When the portion of the elongate member is in the first position, each of the first and second anchor members is at least partially received in the elongate tube. When the portion of the elongate member is in the second position, the first and second anchor members project through the first and second apertures, respectively, and extend transversely relative to a longitudinal axis of the elongate member; the first free distal end is positioned outwardly of the elongate tube at a first angular orientation and the second free distal end is positioned outwardly of the elongate tube at a second angular orientation, with the first and second angular orientations being circumferentially spaced from one another about the elongate tube.

As noted above, Simon's biopsy needle-guide includes a hollow cannula with an open end 18. The open end 18 is necessary for the sharpened distal tip 52 to extend out of the cannula 12 while the device is being positioned. Retracting it back into the cannula after deploying the pincer protects the wire 50 from a biopsy needle, which is aimed at the distal end of the cannula (column 11, line 52 – column 12, line 2). Claim 32, however, calls

for an elongate tube with a closed distal end. Accordingly, claim 32 is distinguishable from Simon.

Claim 32 is unobvious over Simon, as well. Given the detailed explanation of the pitfalls of hookwire designs in Simon, nothing in the applied art would lead one skilled in the art to contradict Simon's explicit solution to those pitfalls. Furthermore, closing the end of the cannula 12 of Simon's guide would prevent it from operating as intended; modifying a reference in a manner that would destroy its utility or materially alter its method of operation is inherently unobvious. Claim 32, therefore, is patentable over Simon either viewed alone or in combination with Tanaka and/or Hawkins. As claims 33-36, 65, 66, 68, and 70-74 depend from claim 32, they are patentable at least by virtue of their dependence from a patentable base claim.

IV. Claims 75, 76, 78, 79, and 82

Claim 75 defines a tissue anchor for stabilizing a tissue mass for surgical excision. This tissue anchor generally includes an elongate tube, a manually controllable actuator, and a plurality of manually deployable anchor members. The elongate tube has a central bore, a wall, a tapered distal portion that defines a closed distal end adapted to be advanced into the tissue mass, and a plurality of apertures extending through the tapered distal portion. The actuator is carried by the elongate tube and comprises an elongate member sized for a close sliding fit within the central bore of the elongate tube. The actuator is moveable with respect to the elongate tube between a first position and a second position. One of the anchor members is associated with each aperture of the elongate tube. Each anchor member is operatively connected to the actuator such that it assumes a retracted position when the actuator is in its first position and it assumes an extended position when the actuator is in its second position. In its retracted position, each anchor member has a major portion received within the central bore of the elongate tube; in its extended position, each anchor member projects outwardly from its associated aperture into the tissue mass and assumes a curved configuration to facilitate stabilization of the tissue mass.

As noted above, the cannula 12 of Simon's biopsy needle-guide must have an open distal end 18 to operate as intended and solve the problems Simon sees in prior art devices. Since claim 75 requires that the elongate tube have a tapered distal portion that defines a closed distal end, though, it is distinguishable from Simon. Nothing in the applied art would lead a skilled artisan to contradict Simon's explicit teachings to provide a tissue anchor having an elongate tube that would not operate as Simon intends. Claim 75 and dependent claims 76, 78, 79, and 82, therefore, are patentable over the applied art.

IV. Claims 80, 81, 83-87, 92 and 98

Aspects of independent claims 80, 83, 92, and 98 are analogous to aspects of claim 75 discussed immediately above. By analogy to the preceding discussion, claims 80, 83, 92, and 98 are patentable over the applied art, as are dependent claims 81 and 84-87.

V. Conclusion

In view of the foregoing, the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (206) 359-3848.

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Respectfully submitted,

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